

Psychosometric Properties of the Filipino Version of the International Consultation on Incontinence Questionnaire-Male Lower Urinary Tract Symptoms and Female Lower Urinary Tract Symptoms

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Objective: This purpose of this study was to translate the International Consultation on Incontinence Questionnaire-Male Lower Urinary Tract Symptoms (ICIQ-MLUTS) and Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) into Filipino and determine its psychosometric properties mainly feasibility, internal consistency (reliability), and stability (test-retest reliability).

Methods: This was an observational, non-interventionist study, which recruited 100 male and 100 female patients seeking consult at the Philippine General Hospital for lower urinary tract symptoms. The questionnaires were completed in a single visit with the exception of 20 patients who were asked to answer the questionnaire again after 2 weeks to evaluate test-retest reliability. The ICIQ-MLUTS Filipino questionnaire is a 14-item self-administered questionnaire while the ICIQ-FLUTS Filipino questionnaire is a 13-item self-administered questionnaire.

Results: There was an 81% completion rate for the ICIQ-MLUTS questionnaire and 100% completion rate for the ICIQ-FLUTS questionnaire. Reliability testing revealed Cronbach's alpha coefficient of 0.949 for the ICIQ-MLUTS and 0.956 for the ICIQ-FLUTS questionnaire while test-retest reliability showed intraclass coefficient values above 0.9 for individual items of both questionnaires.

Conclusion: The Filipino versions of the ICIQ-MLUTS and ICIQ-FLUTS questionnaires show adequate feasibility, reliability and validity.

Key words: male lower urinary tract symptoms (MLUTS), female lower urinary tract symptoms (FLUTS), quality of life, questionnaire, validity

Introduction

Lower urinary tract symptoms (LUTS) include storage, voiding and post-micturition symptoms, primarily due to Benign Prostatic Obstruction (BPO) and other pathologies along the urethra, sphincter, prostate and bladder.¹ It is a combination of symptoms, which are non-sex-

specific, sometimes age-related and progressive, and usually have overlapping underlying pathophysiologic mechanisms.² Worldwide, it has a prevalence of 60-70%, while more than 50% of Asians are affected.³ It has traditionally been measured using the International Prostate Symptom Score (IPSS). There is no marked cultural variation with regards to overall prevalence

of LUTS. Below the 40-year old age group, LUTS is more common in women than in men, in contrast to the above 40-year old age group.⁴ However, studies have shown that it is unable to distinguish bladder outlet obstruction from detrusor instability.⁵

In 1998, the International Continence Society (ICS) held the 1st International Consultation on Incontinence (ICI) and International Consultation on Urological Diseases (ICUD), wherein the development of a universally applicable questionnaire was put into vision.⁶ The International Consultation on Incontinence Questionnaire (ICIQ) advisory board was then formed to guide the development of these questionnaires.

The ICIQ-MLUTS questionnaire is a 14-item self-administered questionnaire evaluating male LUTS and its impact on quality of life (QoL). The symptom question is answered with a 5-point Likert scale while the QoL, with an 11-point Likert scale. Items 2-6 are questions about the voiding symptoms with a minimum score of 0 and maximum score of 25 while items 7-12 are incontinence questions with a minimum score of 0 and a maximum score of 24. The last 2 items are questions on irritative symptoms.

The ICIQ-FLUTS questionnaire is a 13-item self-administered questionnaire evaluating female LUTS and impact on quality of life (QoL). Items 2-6 are questions about the voiding symptoms with a minimum score of 0 and maximum score of 25 while items 7-12 are incontinence questions with a minimum score of 0 and a maximum score of 24. The last 2 items are questions on irritative symptoms.

Translation of the ICIQ questionnaire to foreign languages has been encouraged to provide physicians with a tool, which is conceptually equivalent, equally natural and acceptable, that can be used locally for both research and clinical practice. This study aimed to develop a Filipino version of the ICIQ-MLUTS and FLUTS Questionnaire, following the protocol for translation developed by the ICIQ Advisory Board. It also aimed to evaluate its psychometric properties; mainly feasibility, internal consistency (reliability), and stability (test-retest reliability).

Materials and Methods

The ICIQ-MLUTS and ICIQ-FLUTS questionnaires were sent to the Surian ng Wikang Pambansa (Commission on Filipino Language) and Sentro ng Wikang Filipino-Manila, where two bilingual native Filipinos translated the ICIQ-MLUTS questionnaire into Filipino. Two official bilingual translators, who were not involved in the translation stage, back-translated this Filipino questionnaire into English. The translation and back-translation were sent to the ICIQ Advisory Board for review. After receiving the approval of the ICIQ Advisory Board, the researchers reviewed the translations and back-translations and consolidated the ICIQ-MLUTS Filipino questionnaire.

Thirty bilingual adult males and 30 females were included in the pre-test group. Once consent to participate in the study was given by the participants, they were asked to answer the English and Tagalog versions of the ICIQ-MLUTS questionnaire. After answering the questionnaire, a short structured interview was conducted by the investigator. Questions involved 1) difficulty in understanding the questions, 2) difficulty in understanding the choices, 3) if there were questions that seemed redundant and 4) if there were ways to improve the questionnaire.

Data gathered from the interviews were used to revise the translated questionnaire. The revised questionnaire was validated on 100 consecutive male and 100 female patients >19 years old, able to understand written English and Filipino, who consulted, or were referred to the Urology Service of the Philippine General Hospital for Lower Urinary Tract Symptoms (LUTS) were recruited. Those who were illiterate or with psychological disorders were excluded from the study. Twenty patients asked to return after 2 weeks to re-answer the questionnaires.

Data collated were encoded in Microsoft Office Excel 2011. Results were analyzed for pre-test accuracy, feasibility, face/content-validity, internal consistency (reliability), and stability (test-retest reliability) using Microsoft Office Excel 2011 and IBM SPSS ver 20.

Pre-test accuracy was measured using Intraclass correlation coefficient (ICC). This

evaluated the answers in the 30 pre-test questionnaires: ICIQ-MLUTS and initial ICIQ-MLUTS Filipino questionnaire. Content validity was described in terms of observations given by the pre-test group in their interview.

Date encoded from answers of the 100 ICIQ-MLUTS Filipino questionnaire were analyzed for feasibility, internal consistency and stability. Feasibility was based on the completeness on the items of the questionnaire. Completeness was reported as proportions of values that were answered out of the total number of items. The data were presented in graphical form. Internal consistency was measured using the Cronbach's alpha coefficient. Stability was measured using Intraclass correlation coefficient, using the data from the respondents who were asked to retake the questionnaire after 2 weeks.

The protocol of this study was reviewed and approved by the Ethics Committee of the Expanded Hospital Research Office of the Philippine General Hospital.

Results

The ICIQ-MLUTS Filipino questionnaire (Table 1) is a 14-item self-administered questionnaire while the ICIQ-FLUTS (Table 2) Filipino questionnaire is a 13-item self-administered questionnaire. Each item is divided into a symptom and a QoL question, answerable by a 5-point and an 11-point Likert scale, respectively.

The answers for the initial ICIQ-MLUTS and ICIQ-FLUTS Filipino questionnaires were highly consistent with the ICIQ-MLUTS and ICIQ-FLUTS questionnaires (Table 3). For ICIQ-MLUTS, intraclass correlation coefficient (ICC) was high for most of the questions except for the question on urge incontinence (8A). The question on unexplained urinary incontinence (10A) and nocturnal enuresis (11A) had ICC values of 0.000 since most of the answers were "0" except for one item. Upon interview, it was pointed out that Question 8A, 10A and 11A were vague by most of the respondents and thus were suggested to be rephrased. Question 12A was found to be lengthy and difficult to understand and was almost completely revised, using shorter phrases and more

Table 1. ICIQ-MLUTS* Filipino questionnaire.

Question	
1	Pakisulat ang petsa ng kapanganakan:
2A	Mayroon bang pag-antala sa paglabas ng iyong pag- ihi?
3A	Kailangan mo bang umiri upang magtuluy-tuloy ang pag-ih?
4A	Masasabi mo bang ang lakas ng tulo ng iyong ihi ay...
5B	Paputol-putol ba ang iyong pag-ih?
6A	Gaano kadalas mong nararamdamang hindi pa nauubos lahat ng laman ng iyong pantog matapos umihi?
7A	May mga pagkakataon bang kailangan mong magmadali papuntang banyo upang umihi?
8A	Napapaihi ka ba sa salawal bago ka pa man makarating sa banyo?
9A	Napapaihi ka ba sa salawal sa tuwing ikaw ay umuubo o bumabahing?
10A	Napapaihi ka ba sa salawal kahit walang ginagawa at kahit hindi mo nararamdamang naihi ka?
11A	Napapaihi ka ba sa salawal kapag tulog ka?
12A	Pagkatapos mong umihi, gaano kadalas na napapaihi ka pa ulit sa iyong salawal?
13A	Ilang beses ka umihi sa araw?
14A	Sa gabi, ilang beses kang bumabangon para umihi?

*International Consultation on Incontinence Questionnaire-
Male Lower Urinary Tract Symptoms

Table 2. ICIQ-FLUTS* Filipino questionnaire.

Question	
11	Pakisulat ang petsa ng kapanganakan:
2A	Sa gabi, ilang beses ka bumangon para umihi?
3A	May mga pagkakataon bang kailangan mong magmadali papuntang banyo para umihi?
4A	Nakakaramdam ka ba ng pagsakit ng iyong pantog?
5B	Ilang beses ka umihi sa isang araw?
6A	Mayroon bang pag-antala sa paglabas ng iyong pag- ihi?
7A	Kailangan mo bang umiri para upang makaihi?
8A	Paputol-putol ba ang iyong ihi?
9A	Napapaihi ka ba sa salawal bago ka pa man makarating sa banyo?
10A	Gaano kadalas na hindi mo mapigilan ang pagtulo ng iyong ihi?
11A	Napapaihi ka ba sa salawal kapag ikaw ay aktibo, napupuwera, umuubo o bumabahing?
12A	Napapaihi ka ba sa salawal kahit walang ginagawa at hindi mo nararamdamang naihi ka?
13A	Napapaihi ka ba sa salawal kahit tulog ka?

*International Consultation on Incontinence Questionnaire-
Female Lower Urinary Tract Symptoms

commonly used words (Table 4). For ICIQ-FLUTS, intraclass correlation coefficient (ICC) was high for most of the questions except for the question on unexplained incontinence (12A). The question on unexplained urinary incontinence (12A) had ICC values of 0.000 since most of the answers were "0" except for one item (Table 5). Upon interview, it was pointed out that Question 2A, 5A, 10A and 13A were vague by most of the respondents and thus were suggested to be rephrased (Table 6).

After revision, the ICIQ-MLUTS and ICIQ-FLUTS questionnaires were given to 100 male and 100 female respondents. The ages of the male respondents ranged from 24 to 86 with a mean age of 63 years. Ninety percent (90%) of the respondents were older than 50 years, half of whom were 61-70 years old. The ages of the female respondents ranged from 19 to 79 with a mean age of 57 years. More than half of the respondents were more than 60 years old.

Table 3. Accuracy of initial ICIQ-MLUTS Filipino questionnaire.

Question	ICC*	Quality of Life	ICC
2A: Hesitancy	0.953	2B	0.996
3A: Straining	0.972	3B	0.978
4A: Weak Stream	1.000	4B	0.986
5A: Intermittency	1.000	5B	1.000
6A: Incomplete Void	0.849	6B	0.980
7A: Urgency	0.983	7B	0.970
8A: Urge Incontinence	0.768	8B	0.950
9A: Stress Incontinence	0.921	9B	0.794
10A: Unexplained Incontinence	0.000	10B	0.482
11A: Nocturnal Enuresis	0.000	11B	1.000
12A: Post-micturation Dribbling	1.000	12B	0.995
13A: Frequency	1.000	13B	1.000
14A: Nocturia	0.986	14B	0.998

*Intraclass Correlation Coefficient

Table 5. Accuracy of initial ICIQ-FLUTS Filipino questionnaire.

Question	ICC	Quality of Life	ICC
2A: Nocturia	0.976	2B	0.994
3A: Urgency	0.900	3B	0.965
4A: Suprapubic pain	0.955	4B	0.996
5A: Frequency	0.982	5B	0.984
6A: Hesitancy	0.970	6B	0.998
7A: Straining	0.932	7B	0.801
8A: Intermittency	0.894	8B	0.906
9A: Urge Incontinence	0.887	9B	0.870
10A: Incontinence	0.864	10B	0.857
11A: Stress Incontinence	0.990	11B	0.987
12A: Unexplained Incontinence	0.000	12B	0.000
13A: Nocturnal Enuresis	0.794	13B	1.000

Table 4. Comments and recommendations of the respondents on the initial version of the ICIQ-MLUTS Filipino questionnaire.

Difficulty in understanding the questions	MLUTS - Question 7A: Replaced the word "kumaripas (dash)" with "magmadali (hurry)" - Question 8A, 9A, 10A, 11A: Replaced the phrase "Tumutulo ba ang iyong ihi (does your urine drip)" with "Napapaihi ka ba sa salawal (do you void in your pants accidentally)" - Question 12A: The question is too lengthy and hard to understand. Revised "bahagyang basa sa iyong pantalon (slight wetting of pants)" with "napapaihi ka bigla sa salawal (involuntarily void in your trousers)" and deleted "nagkapagsuot na ng pantalon (after wearing pants)"
Difficulty in understanding the choices	MLUTS Question 4A: The 2nd and 3rd choices are almost similar. Replace "paminsan-minsan (occasionally)" with "bihira (rarely)"
Redundant questions	None
How to improve the	- The questionnaire is difficult to read, especially those with poor eyesight. The size of the text should be enlarged. - The font size of the choices and the spaces in-between should be widened.

Table 6. Comments and recommendations of the respondents on the initial version of the ICIQ-FLUTS Filipino questionnaire.

Difficulty in understanding the questions	FLUTS • Question 2A: Replaced the phrase "gaano kadalas na kailangan mong bumangon upang umihi (how many times do you need to go up in order to urinate)?" with "ilang beses ka bumangon para umihi (how many times do you get up to urinate)?" • Question 5A: Replaced the phrase "Gano ka kadalas umihi sa araw? (how often do you urinate during the day)" with "Ilang beses ka umihi sa araw? (How many times do you urinate during the day)" • Question 10A: Replaced the word "tumatagas (leaking)" with "hindi mo mapigilan ang pagtulo ng iyong ihi (unable to hold your urine)" • Question 13A: Revised "Tumutulo ba ang iyong ihi bago kapag tulog ka (Does your urine leak during sleep)" with "Napapaihi ka ba sa salawal kahit tulog ka (Do you involuntarily void even during sleep)".
Difficulty in understanding the choices	• None
Redundant questions	• None
How to improve the questionnaire	• The questionnaire is difficult to read, especially those with poor eyesight. The size of the text should be enlarged. • The font size of the choices and the spaces in-between should be widened.

Eighty one respondents were able to answer the ICIQ-MLUTS Filipino questionnaire completely. Twelve respondents missed answering 1 item while the rest missed 2 items. The missed items were mostly Quality of Life questions, usually after answering a value of "0" for the Symptom questions. All of the respondents were able to answer the ICIQ-FLUTS Filipino questionnaire completely. However, there were 10 respondents who did not give their date of birth.

The reliability of the ICIQ-MLUTS Filipino questionnaire was high (Cronbach's alpha = 0.949). The same is true for the ICIQ-FLUTS Filipino questionnaire with a Cronbach's alpha value of 0.956. Corrected item-total correlations were also high for all of the items.

The ICIQ-MLUTS questionnaire has a high stability with ICC values above 0.9. The ICIQ-FLUTS questionnaire also has a high stability with ICC values above 0.9 except for Unexplained Incontinence (12A) and Nocturnal Enuresis (13A). This shows that scores for individual items were reproducible for the same case under the same conditions after an interval of 2 weeks.

Discussion

This study presents a Filipino version of the ICIQ-MLUTS and ICIQ-FLUTS that demonstrated high intraclass correlation coefficient with the English version.

After results of the pre-test were collated, the researchers modified the initial questionnaire focusing on improving its readability and making it easier for the patients to understand the questions. The goal was to maintain the context of the original English version, while rephrasing it into brief and simpler questions. The font size and tic boxes were maximized since most of the respondents were elderly and visually impaired. Enhancing the readability and comprehensibility of the questionnaire improves the ability of the tool to accurately measure the patient's level of symptom and bother.

Internal validity was high with a Cronbach's alpha coefficient of more than 0.90 for both questionnaires. This is comparable with validation studies of ICIQ-MLUTS questionnaire translations into other languages such as in Portuguese, which is 0.88.⁷ Translations of the ICIQ-FLUTS questionnaire yielded similar results;

English (0.75), Persian (0.75), Greek (0.85) and Arabic (0.97).^{8,9,10,11} Looking at the corrected total-item correlation, no value was below 0.3, meaning that there was no particular item that does not correlate well with the overall scale. All of the questions were worthy of retention and removing any of the questions would not improve the internal validity significantly.

Test-retest reliability for the FLUTS questionnaire was high for most of the questions with ICC values of more than 0.90. Nocturnal enuresis had an ICC value of 0.000 since most of the answers to these questions had an answer of 0. Unexplained incontinence had an ICC value of 0.77, which can be described as low but still acceptable. It shows that the questions produce the same answers over a short period of time. This result is comparable with other validation studies such as in Persian (0.84), Arabic (0.80) and Greek (0.52-0.99).^{9,10,11} Stability is a precursor to measuring the ability of the tool to measure response to treatment. Test-retest reliability for the MLUTS questionnaire was high with ICC values of more than 0.90 for most of the questions. It shows that the questions produce the same answers over a short period of time. This result is comparable with other validation studies with scores ICC values of 0.68 to 0.88.¹²

One limitation of the questionnaire is that its' correlation with current gold standards for LUTS and incontinence were not verified. Individual sections of the questionnaire can be compared with individual tests: the voiding questions can be compared with urodynamic evaluations and incontinence questions can be compared with bladder diaries and pad tests. However, symptom bother cannot be measured by any other available tests today.

Another limitation of the study is that it was not administered to a control group or to individual patient groups. For example, those with primarily bladder outlet problem as verified by urodynamic studies, those with primarily incontinence symptoms verified with bladder diaries and pad tests, and those who have a combination of symptoms comparing them to a set of control patients. This will determine the relationship of individual constructs within the questionnaire.

Responsiveness was also not measured in the study. The questionnaire could be administered to the same two sets of people, one wherein intervention was given and one control and re-administered after 2-4 weeks. This will measure the ability of the questionnaire to respond to treatment after a set period of time.

Conclusion

The ICIQ-MLUTS and ICIQ-MLUTS Filipino questionnaires show adequate feasibility, reliability and stability. Their internal validity was high with a value of more than 0.9. There is adequate retest reliability with ICC values of more than 0.90 for most of the items. These can be used for clinical and research activities involving Filipino-speaking patients with LUTS, as initial and monitoring tool to identify individual symptoms and measure its severity. However, it is recommended that further research be done with regards specific patient groups and that its ability to measure responsiveness to treatment be evaluated.

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